IBRAMED

QUESTÃO DE RESPEITO

Instructions Manual

DERMOTONUS ESTHETIC

Manufactured by IBRAMED
Indústria Brasileira de Equipamentos Médicos EIRELI
ANVISA Nº 10360319003
4th edition (LAST REV_07/2013)

TABLE OF CONTENTS

SYMBOL DEFINITIONS.....3
CARTON.....4
ABREVIATIONS GLOSSARY 4
FIGURES GLOSSARY.....5
FOREWORD.....6
PRODUCT DESCRIPTION.....6
ESSENTIAL PERFORMANCE 6
SAFETY PRECAUTIONS.....7
PRECAUTIONARY DEFINITIONS.....7
INDICATIONS, CONTRAINDICATIONS AND PRECAUTIONS.....9
INDICATIONS FOR USE.....9
CONTRAINDICATIONS.....9
PRECAUTIONS.....10
GENERAL EQUIPMENT CARE.....11
SHIPPING DAMAGE.....11
INSTALLATION INSTRUCTIONS.....11
INSTALLATION, CARE AND CLEANING.....11
CARE EQUIPMENT.....11
CLEANING OF DERMOTONUS ESTHETIC.....12
ENVIRONMENTAL PROTECTION.....13
ELECTRICAL FEED.....14
NOTES.....14
ELECTROMAGNETIC COMPATIBILITY GUIDANCE.....15
SPECIFICATIONS.....23
SYSTEM SPECIFICATIONS.....23
VACUUM SPECIFICATIONS.....23
NOMENCLATURE.....27
CONTROLS, INDICATORS AND CONNECTIONS.....27
DEFINITION OF SYMBOLS.....30
MECHANICAL MASSAGE.....31
ACESSORIES USED.....31
MICRODERMABRASION.....32
PREPARING DEVICE.....33
OPERATION INSTRUCTIONS.....33
SELECTION OF PARAMETERS.....33
PROGRAMMING THE TREATMENT TIME.....33
PROGRAMMING EQUIPMENT.....34
PATIENT PREPARATION.....35
TECHNICAL APPLICATION 36
MICRODERMABRASION.....36
REFERENCES.....38
ACESSORIES ACCOMPANYING DERMOTONUS ESTHETIC.....40
REPLACEMENT ACCESSORIES.....40
TROUBLESHOOTING.....41
TECHNICAL ASSISTANCE.....43
CEFAI – IBRAMED Center for Education and Advanced Training.....44

SYMBOL DEFINITIONS

BELOW ARE THE DEFINITIONS OF THE SYMBOLS USED ON THE EQUIPMENT AND THROUGHOUT THE INSTRUCTIONS FOUND IN THIS MANUAL. UNDERSTAND THESE SYMBOLS AND THEIR DEFINITIONS BEFORE OPERATING THIS EQUIPMENT.

Caution! Refer to user manual.

Equipment with applied part of BF type.

Dangerous Voltage.

CLASS 1

CLASS 1 equipment. It has grounding resources for protection .

IPXO

Equipment not protected against harmful water penetration.

Applicator pen for aluminum oxide jet (microdermoabrasion)

Vaccum cupping applicator.

Start treatment.

Stop treatment.

It indicates: Off (no electric voltage)

It indicates: On (with electric voltage)

Sensitivity against electrostatic discharge.

V~

Alternating Current.

~ line

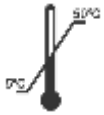
Electric network in Alternating Current

SYMBOL DEFINITIONS

CARTON

FRAGILE: The content in this package is fragile and must be transported carefully.

This side up.


Limits of temperature for storage and packaging in °C (Celsius Degrees).

Keep away from the rain.

Do not stack up.

Do not use if the packaging is damaged.

Check the operating instructions.

Indication of the maufacturer’s name and address.

ABREVIATIONS GLOSSARY

VA	Volt Ampere
A	Ampere
mm	Millimeter
V~	Volts in Alternating Current
cm	Centimeter
mmHg	Millimeters of Mercury
Hz	Hertz
Volts	Voltage
min	Minute
s	Second
Kg	kilogram
°C	Degrees Celsius

FIGURES GLOSSARY

Figure 1. Upper view.....26
Figure 2. Frontal View.....27
Figure 3. Rear View.....27
Figure 4. Cupping applicator with protective screen pads, with connection for body glass cupping applicators.....30
Figure 5. A, Cupping applicator (60mm diameter) for decontracting maneuvers (pulsed mode); **B**, spherical cupping adaptor for massage (continuous mode).....30
Figure 6. A, Medium roller applicator (60mm diameter); **B,** small roller applicator (50mm diameter).....30
Figure 7. A, glass bulb facial cupping applicator; **B,** straight bulb facial cupping applicator; **C,** 12 mm cylinder facial cupping applicator; **D,** duckbill facial cupping applicator; **E,** 18mm cylinder facial cupping applicator.....30
Figure 8. A, Microdermabrasion: large 75 micron diamond tip, small 100 micron diamond tip, small 150 micron diamond tip, respectively; **B,** pen for diamond tip.....31
Figure 9. Crystal Peeling diamond pen.....31
Figure 10. A, B and **C** equipment presentation messages..32
Figure 11. Liquid Crystal Display, equipment default.....33
Figure 12. Liquid crystal display example 1, parameter adjustment -application time (20 minutes).....33
Figure 13. Facial application technique with diamond tip pen –Diamond Peeling.....35
Figure 14. Facial application technique with crystal peeling pen.....35
Figure 15. Body application technique with crystal peeling p en.....35
Figure 16. A, B and **C,** body application technique with cupping spheres.....36

This user manual allows the user to efficiently use the **DERMOTONUS ESTHETIC.**

Refer to academic literature for further information on the uses of mechanical massage and vacuum therapy and the two modes of microdermabrasion: crystal peeling and diamond peeling before any treatment on a patient.

Users must read, understand and follow the information in this manual for each mode of treatment available, as well as the indications, contra indications, warnings and precautions.

The specifications and instructions in this manual are in effect at the time of its publication. These instructions may be updated at any time at the manufacturer's discretion. Visit our website for updates.

ESSENTIAL PERFORMANCE

DERMOTONUS ESTHETIC is a device which allows treatments in the Health, Medical and Cosmetic areas, and which does not present systemic side-effects or causes dependency. **DERMOTONUS ESTHETIC** is a multifunctional equipment, used in the techniques of mechanical massage and vacuum therapy and in two modes of microdermabrasion: crystal peeling and diamond peeling.

PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment prior to therapy session.

Text with a "CAUTION" indicator refers to potential safety infractions that could cause minor to moderate injury or damage to equipment.

Text with a "WARNING" indicator refers to potential safety infractions that could cause serious injury and equipment damage.

Text with a "DANGER" indicator refers to potential safety infractions that represent immediately life threatening situations that would result in death or serious injury.

- Read, comprehend and practice the precaution and operation instructions. Know the limitations and dangers associated with the use of any electrical stimulation. Observe the precaution and operation labels placed on this unit.
- Do not operate this unit in an environment where other devices intentionally radiate electromagnetic energy in an unprotected manner.
- The equipment must not be stacked and/or placed next to other equipment.
- Check the cables and connectors before each use.
- Do not use sharp pointed objects, such as pencils or pens to operate the keys on the interface with the operator, it can damage the equipment.
- Hold the applicator carefully. The inadequate use of the applicator may adversely affect its characteristics.
- The **DERMOTONUS ESTHETIC** stimulator is not designed to prevent the penetration of water and other liquids. Penetration of water and other liquids may cause malfunction of the internal components of the system, and consequently, promote risk of injure to the patient.
- Disconnect the plug from the power outlet when the device is not used for long periods of time.

WARNING

- In order to be protected from the risk of fire, use only spare fuses of the same type and class.
- Before treating the patient, it is necessary to know the operational procedures for each treatment mode available, as well as the indications, contra indications, warnings and precautions. Refer to other sources to obtain additional information on electrotherapy applications.
- To avoid electrical shock, turn the device off the power supply line before any maintenance procedure.
- **DERMOTONUS ESTHETIC** treatment must not be applied on or next to cancerous lesions.

RESPONSIBILITY FOR USE ELECTROMEDICAL EQUIPMENT

The professional properly certified will be responsible for the use and operation of the equipment. IBRAMED does not make any representations referring to federal, state or local laws which may apply to the use and operation of any electromedical equipment.

The doctor or person under his orders, and also the physiotherapist or other licensed professional in the field, takes all responsibility and full commitment in hiring the credentials required by law for the clinical use and operation of this equipment.

The use of electromedical equipment must follow the federal, state and local norms of each country.

INDICATIONS FOR USE

Indications of mechanical massage:

- Treatment of cellulites and localized fat
- Treatment of adherences and scarring
- Pre and post-operative plastic surgery
- It promotes body remodeling and liquid mobilization of body liquids
- It favors the lymphatic drainage and the elimination of toxins
- It enables the extraction of blackheads during the skin cleansing
- Lifting and facial toning
- Treatment of stretch marks
- Treatment of myofascial pain and fibromyalgia
- Burns, lymphedema among others.

Indications for microdermabrasation

- Photorejuvenation - prevention and treatment
- Reduction of expression lines (thin and medium wrinkles)
- Treatment of hyperkeratosis
- Treatment of striae (stretch marks)
- Pigmentary disorders - melasma, blemishes and hipercromies.
- Scars
- Enlarged pores and microcomedones

CONTRAINDICATIONS

It is not recommended to perform the mechanical massage:

- On skin tumor regions
- Inflammatory rheumatism with fever
- Dermatosis
- Excessive capillary fragility
- Avoid the use in cardiac patients or patients with pacemaker
- Avoid the application during pregnancy, especially in the lumbar and abdominal regions

Contraindications - Not recommended to perform microdermabrasion

- Acne lesions and pustules.
- Cold sores: vesicular-bullous lesions caused by viruses (Herpes virus hominis HVH).
- Rosacea: chronic inflammatory vascular disease characterized by erythema, telangiectasia (fine reddish blood vessels), edema and papules that may be accompanied by pustules and nodules.
- Capillary fragility: blood vessels called capillaries that break easily, causing red spots on the skin.
- Psoriasis: skin disease autoimmune considered chronic,

hyperproliferative of skin of unknown etiology. It has great variety in severity and distribution of skin lesions.

• Diabetes Mellitus: systemic metabolic disease which can cause microvascular complications affecting regeneration and tissue renewal.

• Eczema: disease of the skin that looks red, dry, flaking and itching, also known as atopic dermatitis.

• Lupus erythematosus: a chronic multisystemic inflammatory disease of unknown cause and of autoimmune nature that affects the microcirculation and makes regeneration and tissue renewal difficult.

• Recent use of isotretinoin (up to 6 months after treatment): a medication used to treat severe acne. Its use makes the skin sensitive, which can induce the formation of cracks and injuries during microdermabrasion.

• Immediately after sun exposure.

PRECAUTIONS

• After the procedure it is common for the patient to develop redness/hyperemia (sometimes slightly swollen) and hypersensitivity.

• Eventually scabs may be formed; they should not be taken out in order to avoid staining and / or scarring.

• Avoid using creams or lotions containing acid for one month before the procedure.

• Avoid direct sun exposure after treatment.

• Use of moisturizer and sunscreen.

SHIPPING DAMAGE

Your **DERMOTONUS ESTHETIC** is shipped complete in one carton. Upon receipt, inspect carton and unit for visible and hidden damage. In case of damage, keep all shipping materials including carton and contact the shipping agent responsible for the delivery of the unit. All claims relating to damage during transport should be filed directly with them. The manufacturer will not be liable for any damage during shipping, nor allow for adjustments unless proper formal claim has been filed by the receiver against the carrier. The carton in which your **DERMOTONUS ESTHETIC** was received is specially designed to protect the unit during shipping. Please keep all shipping materials in case you need to return your unit for servicing.

INSTALLATION INSTRUCTIONS

1. Connect the line cord to the back of the **DERMOTONUS ESTHETIC.**
2. Plug the line cord into a grounded wall outlet (100-240 V - 50/60 Hz).
3. Plug the accessories into the correct connections.
4. Switch on your equipment.

EQUIPMENT CARE

- Avoid areas subject to vibrations.
- Install the equipment on a firm and level surface, in open air.
- Do not block ventilation.
- Position the power line cable in a way that it is free, out of places where it might be tread on, and do not place any piece of furniture over it.
- Avoid humid, hot and dusty environments.
- Do not insert objects into device holes.
- The equipment does not need to be used in armored places.

CAUTION

The correct installation, operation and maintenance of the equipment prevent safety risks.

CLEANING OF DERMOTONUS ESTHETIC

The cleansing of the equipment must be performed daily, or in case of need, immediately after use. Do not place the system immersed in liquids. Do not use volatile substances (benzene, alcohol, thinner or solvents in general) to clean the cabinet, because they might damage the finishing coat. Disconnect the equipment from the electrical feed source clean it with a clean cloth humidified in water and mild antibacterial soap.

Applicator cleansing

After using the applicators, cleansing can be carried out in ultrasonic sink and then wash them in running water. For their disinfection, use cotton humidified with aqueous chlorhexidine at 0,5%. Do not use volatile substances (benzene, alcohol, or solvents in general) to clean the acrylic parts. The metallic parts may be autoclaved.

DERMOTONUS ESTHETIC is an electronic device and has heavy metal parts such as lead. So, there are risks of contamination to the environment associated with the discharge of this device and its accessories at the end of their service life. **DERMOTONUS ESTHETIC**, its parts and the accessories must not be disposed of as urban residues. Contact the local distributor to obtain information about norms and laws relative to the elimination of electrical residues, electronic equipment and their accessories.

CAUTION

The device and its consumable parts must be eliminated, at the end of their service life, according to the federal, state or local norms of each country.

DERMOTONUS ESTHETIC is monophasic equipment. The 127/220 volt switching is automatic. There is no need to be worried with the local voltage. Just plug in the device and the equipment will automatically select either 127 Volts or 220 Volts. The connecting cable is detachable and it has tripolar plug with a spe-cial connection used as ground protection for the metallic parts of the equipment. Thus, the place for the equipment installation should have power plug with protective ground terminal. The equipment uses the power plug as a resource to separate its circuits in relation to the power network in all the poles.

NOTES

In the rear part of **DERMOTONUS ESTHETIC** there is a protection fuse. To replace it, **turn the equipment off of the mains voltage line and with a screwdriver**, remove the protection lid, disconnect the fuse and perform the replacement, then replace the protection lid.

Always use the fuses indicated by Ibramed. Use the fuse for the nominal current of 5.0A, operation tension 250V~ and snap action model 20AG (rupture current of 50A).

DERMOTONUS ESTHETIC does not need any type of current stabilizer. Never use power stabilizers.

Before turning on **DERMOTONUS ESTHETIC**, make sure:

- The tension and frequency of the local mains voltage is equal to the one described on the label of power line and tension characteristics located in the rear part of the equipment.
- To prevent electrical shock, do not use the plug in the equipment as an extension cable, or other types of plugs except the terminals fit completely in the receptacle.
- Cleansing and disinfection must be performed with the power plug disconnected from the mains voltage.
- Maintenance and technical assistance of **DERMOTONUS ESTHETIC** must always be performed at an authorized technical service only by qualified technicians.

CAUTION

Inside the equipment there are dangerous tensions. Never open the equipment.

CAUTION

- The use of this unit in places where there is risk of explosion, such as anesthesia departments, or in the presence of anesthetic mixture inflammable when in contact with air, oxygen or nitrous oxide. Equipment not an AP or APG category.
- The use of cables, electrodes and other accessories from other manufacturers and/or different from those specified in this manual, as well as the replacement of internal components of **DERMOTONUS ESTHETIC** may result in increase in emissions or decrease in the equipment immunity.
- **DERMOTONUS ESTHETIC** is designed for use only by professionals in the Health field.
- Radiofrequency communication equipment, mobile or portable, may cause interference and affect the functioning of **DERMOTONUS ESTHETIC**.

POTENTIAL ELECTROMAGNETIC INTERFERENCE

As for the limits of electromagnetic interference, **DERMOTONUS ESTHETIC** is Group 1 Class A electromedical equipment.

The operation at a short distance (1 meter, for example) of short wave or microwave therapy equipment may produce instability in the equipment output. In order to prevent electromagnetic interference, we suggest that one group of the power line is used for **DERMOTONUS ESTHETIC**, and another, separate one for the short wave or microwave equipment.

We also suggest that the patient, **DERMOTONUS ESTHETIC,** and the connection cables are installed at least 3 meters away from shortwave or microwave therapy equipment.

ELETROMAGNECTIC COMPATIBILITY

The electromedical devices demand special attention regarding electromagnetic compatibility (EMC) and must be installed and operated according to the EMC information provided as follows:

<table>
<tr><th colspan="3">Manufacturer’s guidelines and declaration – Electromagnetic emissions</th></tr>
<tr><td colspan="3">The DERMOTONUS ESTHETIC is intended for use in the electromagnetic environment specified below. The customer or the user of the DERMOTONUS ESTHETIC should ensure that it is used in such an environment.</td></tr>
<tr><th>Emission Test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF Emissions
NBR IEC CISPR 11
IEC CISPR 11</td><td>Grupo 1</td><td>The DERMOTONUS ESTHETIC must emit electromagnetic energy in order to perform it’s intend function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF Emissions
NBR IEC CISPR 11
IEC CISPR 11</td><td>Class A</td><td rowspan="3">The DERMOTONUS ESTHETIC is suitable for use in all establishments other than domestic those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Class A</td></tr>
</table>

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **DERMOTONUS ESTHETIC** is intended for use in the electromagnetic environment specified below. The customer or the user of the **DERMOTONUS ESTHETIC** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	± 6 kV by contact ± 8 kV by air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transitories/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV diferencial mode ± 2 kV common mode	± 1 kV diferencial mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Voltage dips, short interruptions and voltage variations in power input lines IEC 61000-4-11	< 5% U_T (> 95% voltage drops in U_T) 0,5 by cycle 40% U_T voltage drops in (60% U_T) by 5 cycles 70% U_T (30% voltage drops in U_T) by 25 cycles < 5% U_T (> 95% voltage drops in U_T) by 5 seconds	< 5% U_T (> 95% de queda de tensão em U_T) por 0,5 ciclo 40% U_T (60% de queda de tensão em U_T) por 5 ciclos 70% U_T (30% de queda de tensão em U_T) por 25 ciclos < 5% U_T (> 95% de queda de tensão em U_T) por 5 segundos	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **DERMOTONUS ESTHETIC** requires continued operation during power mains interruptions, it is needed that the **DERMOTONUS ESTHETIC** be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic fild IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to applications of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The **DERMOTONUS ESTHETIC** is intended for use in the electromagnetic environment specified below. The customer or the user of the **DERMOTONUS ESTHETIC** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communication equipment should not be used no closer to any part of **DERMOTONUS ESTHETIC**, including cable than be separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1,2 $\sqrt{P}$ d = 0,35 $\sqrt{P}$ 80 MHz to 800 MHz d = 0,7 $\sqrt{P}$ 800 MHz to 2,5 GHz Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths set by fixed transmitters, such as radio base stations, telephone (cellular/cordless) telephones and land mobile radios, amateur radio, AM / FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location in which the **DERMOTONUS ESTHETIC** is used exceeds the applicable RF compliance level above, the **DERMOTONUS ESTHETIC** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorientation or relocating the **DERMOTONUS ESTHETIC**.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

IBRAMED

Recommended separation distances between the mobile RF communication equipment and DERMOTONUS ESTHETIC

The **DERMOTONUS ESTHETIC** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **DERMOTONUS ESTHETIC** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **DERMOTONUS ESTHETIC** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum power output of transmitter **w**	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 0,35 \sqrt{P}$	800 MHz to 2,5 GHz $d = 0,7 \sqrt{P}$
0,01	0,12	0,035	0,07
0,1	0,38	0,11	0,22
1	1,2	0,35	0,7
10	3,8	1,1	2,2
100	12	3,5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

SYSTEM SPECIFICATIONS

Dimensions

Width	40 cm (15,75" in) ± 5%
Depth	35 cm (13,78" in) ± 5%
Height	108 cm (42,59" in) ± 5%
Standard Weight (with accessories)	25,5 kg ± 5%

Power

Input	100–240 V~	50/60 Hz
Input power	500 VA	
Fuses	2,0 A 250V~(20AG)	
	Fast Action, Rupture capacity 50 A	
Electrical Class	CLASS I	
Electrical Protection	TYPE BF	

Range of temperature during transportation and storage: 5 - 50°C/ 41- 122° F.

Range of operational environment temperature:
5 - 45 °C/ 41- 113° F.

Regulatory Compliance

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-4

VACUUM SPECIFICATIONS

Mode	Continuous Pulse
Pulse Repetition Frequency minute	10 a 50 pulses per
Vacuum Pressure	0 a -550 mmHg (negative pressure)
Pulse Repetition	10 a 50 pulses per minute
OFF Pulse Duration	1 second
Treatment Time	1 a 60 minutes

Mechanical massage

Several terms are used to describe the technique, such as, endermology, vacuum therapy, endermotherapy, dermotonia and mechanical massage. This terminology is exclusive to this field.

Mechanical massage is a technique created from experiments using simultaneously the pressure therapy by negative pressure associated to rollers which use positive pressure destined to massotherapy by "palper roller" (palpate and roll). It promotes circulatory increments: venous as well as lymphatic and conjunctive mobilization tissue by making a deep massage on the skin, superficial fascia and subcutaneous tissue.

Many maneuvers and techniques are possible with this equipment, such as, mechanical massage with rollers, mechanical drainage with roller, mechanical massage with spheres, intermittent massage (discontractive), conjunctive tissue mobilization, reflex massage, esthetic massage among others.

The negative pressure (vacuum) of Dermotonus Esthetic is adjustable and indicated through a vacuum gauge from 0 to -550 mmHg with a choice of either continuous mode operation or pulsed mode (pulse repetition from 10 to 50 pulses per minute, with off pulse duration of 1 second).

The negative pressure intensity applied varies according to the patient's tolerance, generally around -250 to -350 mmHg and the choice of the mode, either continuous or pulsed and if pulsed it is related to the applied technique.

Suggested mode of application (Vaccum Mode)

- Mechanical massage with rollers – continuous mode
- Mechanical drainage with rollers– continuous mode
- Mechanical massage with spheres – continuous mode
- Intermittent Massage (discontractive) – pulsed mode, pulse interval according to the purpose
- Conjunctive tissue mobilization with glass cupping - continuous mode or pulsed mode
- Reflex massage – continuous mode

Physiological effects

- Increase of local blood flow
- Increase of the oxygen supply
- Lymphatic and tissue drainage
- Defibrosing and improvement on the tissue softness
- Tissue toning and decongestion
- Muscle relaxation

Guidelines:

- Mechanical massage must be vigorous with wide movements, keeping the rollers stick to the skin in order to avoid loss of contact.
- As soon as the skin under the roller is hyperemic (reddish), change the direction of the roller, massage parallel to the

treatment. Massage all the region until you reach a uniform hyperemia.

• Mechanical massage must start with pressures according to the patient's level of sensibility to pain.

Microdermabrasion

Peeling is a word of English origin which means flaking, scarification. Microdermabrasion is a non-chemical method of skin peeling rejuvenation that involves a series of separate treatment at intervals ranging from one to two weeks and that can be used in combination with other treatments.

Essential advantages of microdermabrasion in relation to other modes of peeling:

- It can be performed at any time of the year;
- After treatment it is possible to return immediately to normal activities;
- Low operating cost;
- Low risk;
- It potentiates dermocosmetics treatment;
- Painless.

Microdermabrasion can use a probe which carries out the microcrystals blasting (micro-particles) or a pen with a diamond respectively to remove part of the superficial layer of the skin (epidermis), stimulate the synthesis of growth factors and encourage the tissue renewal. The depth of the peeling is related to the negative pressure used in the equipment, the number of passages on the skin and the speed of the probe or pen on the skin.

Both the techniques, the crystal peeling and the diamond peeling, are ideal to prepare the skin for the skin cleansing and for the application of dermocosmetics.

The crystal peeling as well as the diamond peeling can be performed anywhere on the body and the most treated areas: face, neck and hands.

Guidelines

- After the procedure, it is common for the patient to present hypermia (in some cases slight swell-ing) and hypersensitivity.
- Eventually crusts may be formed which should not be taken in order to avoid spots and /or scarring.
- Avoid using creams and lotions containing acid for one month before the procedure.
- Avoid direct sun exposure after the treatment.
- Use sunscreen and moisturizer.

DIAMOND PEELING

The diamond peeling carries out an exfoliation, a sanding of the skin resulting in a clearer, fresher and more youthful skin. The diamond peeling is performed with a probe pen in which a sandpaper is at-tached. The probe is connected to a vacuum device that sucks the skin and presses it against the diamond sandpaper, making the exfoliation more uniform and effective.

CRYSTAL PEELING

The crystal peeling, or microdermabrasion with crystals, is a non-surgical technique of exfoliation which consists of projecting on the skin an amount of microcrystals under assisted pressure. This projection promotes the removal of superficial skin lines, stimulates cell regeneration, enhances the production of collagen and improves skin quality.
A special pen with the possibility of three tips on the surface of the skin is used in the micro-dermabrasion technique. This pen is connected to two tubes (hoses). A tube (the blue hose) is connected to the micro crystal deposit. The other tube (gray hose) is connected to a vacuum pump. This pen projects the micro crystals on the skin and at the same time aspires the projected crystals, the dirt and the skin debris. The intensity of the crystal projection is proportional to the intensity of the vacuum produced by the equipment. The vacuum prevents the spread of the crystals to the surrounding area.

RECOMMENDATIONS

- Always use the screen filter during the vacuum treatments. The protective air filter unit placed with in the equipment associated with the air filter provides a better functioning and durability of the vacuum pump of the equipment. The screen filter and the protective air filter unit should be cleaned at regular intervals.

- Avoid using creams, gels or oil. This may cause damage to equipment.

- The aluminum oxide crystal, when at rest, even tapped and inside its recipient can absorb humidity forming small stones. Therefore, always sieve the crystal before putting it inside the crystal storage tank (15). At the end, the storage tank should be emptied and cleaned..

- The crystal storage tank (15), the waste tank (9), and the protective air and impurity filter unit for the vacuum operating mode (8) have a rubber sealing ring around the screw. Always check if it is in the place before being tapped.

- When it is necessary, or at regular intervals, the filter element of the protective air filter unit of the negative pressure pump should be cleaned (13). To do that, remove the plastic cup spinning it in the counter-clockwise, remove the filter and clean it with soap and water. Once dried, replace the filter element and the plastic cup in the correct place by turning them clock wise.

CONTROLS, INDICATORS AND CONNECTIONS

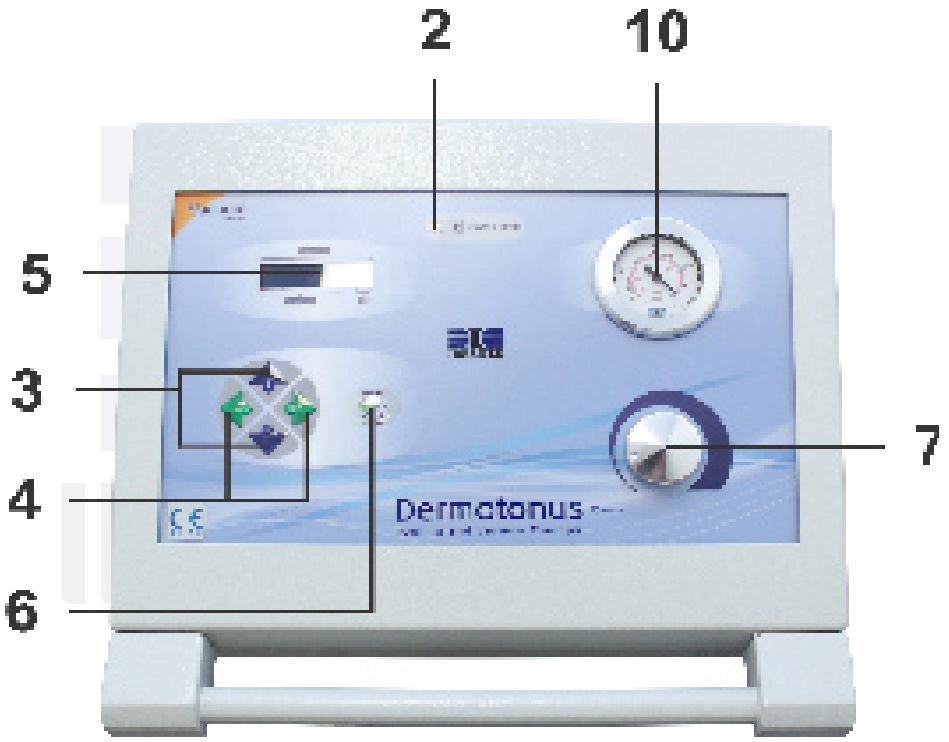


Figure 1. Upper view.

CONTROLS, INDICATORS AND CONNECTIONS

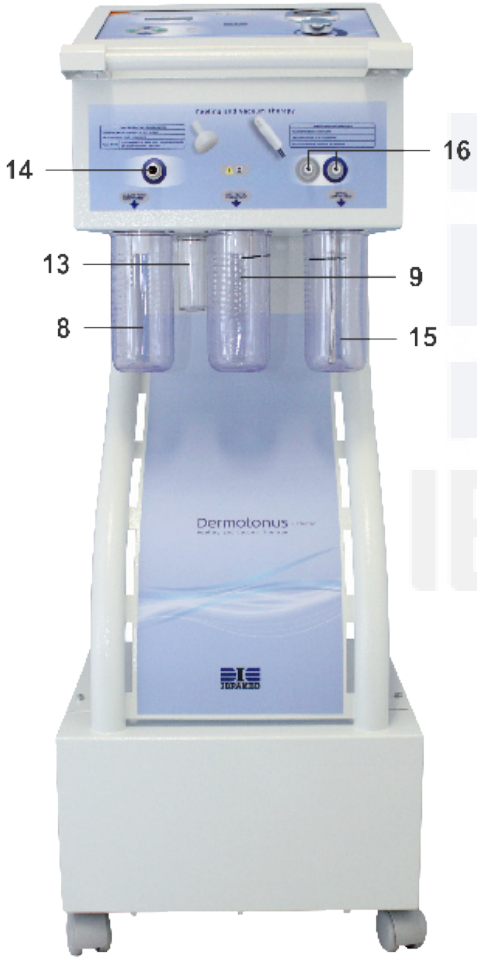


Figure 2. Frontal view.

Figure 3. Rear view.

NOMENCLATURE

1- Power switch**:** **ON/OFF**.

2- Indicator light of the condition "on".

3- Control keys: **SET** – These keys are used to choose the values of the parameters necessary to the application.

4- Control keys: **BACK** and **NEXT.** These keys are used to select the parameter field necessary to the appli-cation.

5- Alphanumeric liquid crystal display.

6- Control keys: **START/STOP**. To start the treatment. STOP for to cease the treatment.

7- Control of intensity adjustment of vacuum.

8- Protective air and impurities filter unit for the vacuum operating mode (Vacuum).

9- Waste container of used aluminum oxide crystal.

10- Indicator of the vacuum quantity (vacuum gauge).

11- Protection fuses.

12- Power cable to be connected in the electrical network.

13- Protective unit air filter of the pump of negative pressure.

14- Spiral-shaped hose connection of negative pressure which is connected to either the vaccum cupping or to the pen for diamond peeling. These connections operate like a "quick coupling". Just press the metal ring and pull so that and the piece is released. To couple it again just press the hose against the piece.

15- Storage tank unit of aluminum oxide crystal.

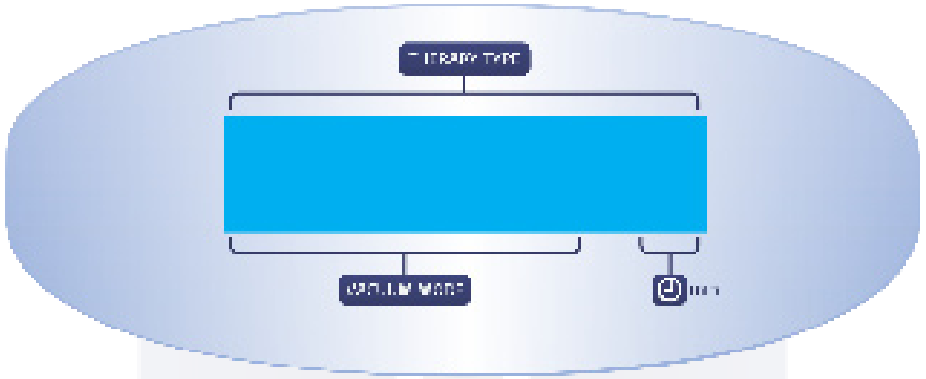
16- Negative pressure of double connection hose (gray and blue) which is connected to the applicator pen of aluminum oxide jet. The blue hose is the crystal conductor and the gray one is the vacuum conductor. Never reverse the hoses.

17- Rating plate of voltage and fuses.

18- General characteristic board.

DEFINITION OF SYMBOLS

Read and understand these symbols and their definitions before operating the equipment



THERAPY TYPE

Therapy types: either vacuum or peeling.

Switch used to start or stop treatment. Always press the center of the switch.

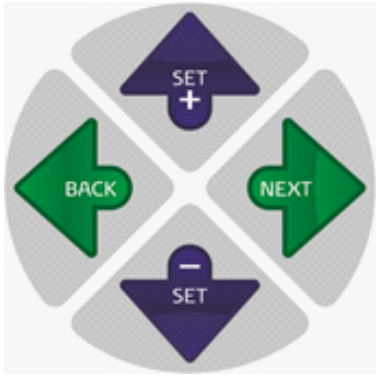
VACUUM MODE

Vacuum mode operation: either continuous or pulsed

Selection of parameters:

Timer: programmable treatment time from 1 to 60 min.

Vacuum intensity control from 0 to -550 mmHg (negative pressure).



MECHANICAL MASSAGE

Figure 4. Adapter with screen protector pads with connection to the applicator body suction cup and glass applicators.

Body accessories for connection of cupping :

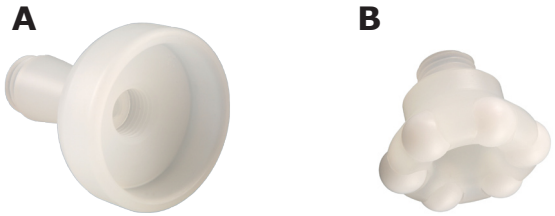


Figure 5. **A**, Cupping applicator (60 mm diameter) for discontractive maneuvers (pulsed mode);
B, cupping adapter with spheres (continous mode).

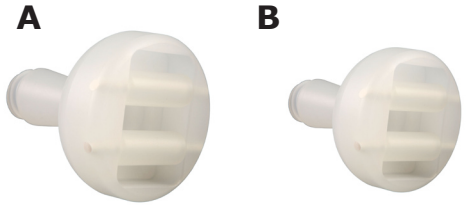


Figure 6. A, medium roller applicator (60 mm diameter) and B, small roller applicator (50 mm diameter).

Figure 7. A, glass sucker bird; **B, ,** Glass suction cup applicator facial straight birdie; **C,** Facial cupping glass applicator (12mm); **D**, Applicator facial glass sucker duck's bill; **E**, Facial cupping glass applicator (18mm).

MICRODERMABRASION

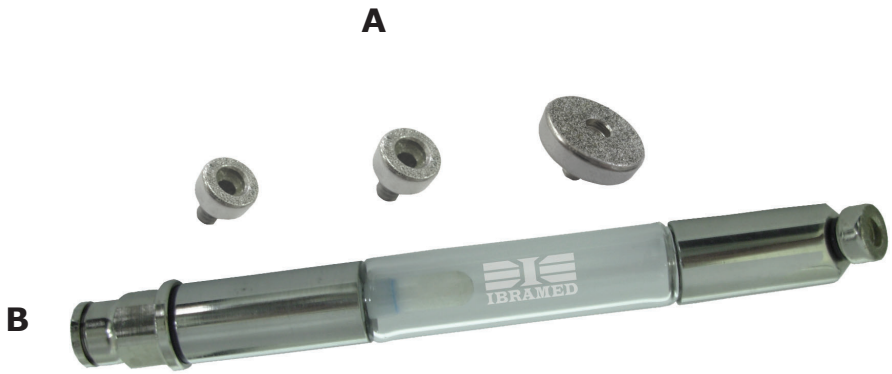


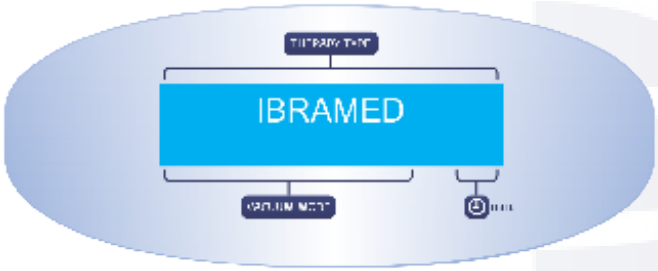
Figure 8. A, Sandpaper for microdermabrasion: small diamond tip of 150 microns, small diamond tip of 100 microns, large diamond tip of 75 microns respectively; **B**, Stylus with diamond tip.

Figure 9. Pen crystal peeling

PREPARING DEVICE

Check if the power cable is connected to the electrical feed source on the wall. Press the **ON/OFF** key to the **ON** position. The display will show the presentation message for a few seconds, followed by the **DERMOTONUS ESTHETIC** standard default screen.

A



B

C

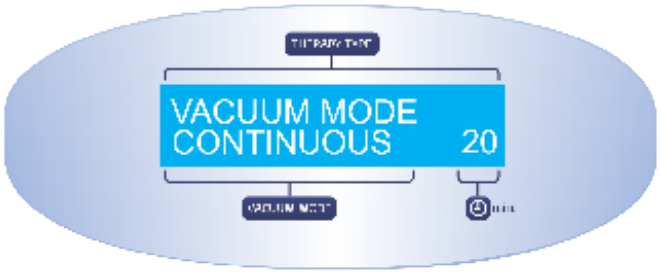


Figure 10. A, **B** and **C** Liquid crystal display with the messages of presentation.

SELECTION OF PARAMETERS

The **BACK/NEXT** keys allow you to select the parameters necessary for the treatment. Press the keys in the cursor to move to the next parameter or take the cursor back to the previous parameter. The **SET+** and **SET-** keys allow you to select the parameters necessary for the treatment.

PROGRAMMING THE TREATMENT TIME

Program the desired time of session, the application time can be adjusted from 1 to 60 minutes. At the end of the programmed time the equipment will turn off the emission automatically.

Start Treatment
Press **START** to begin therapy.

Stop Treatment
Press the **STOP** button to end the therapy.

Intensity of Vacuum

The intensity of vacuum can be increased or decreased at any given time during the session. After pressing the **START** key, turn the vacuum intensity control and adjust as necessary, and if you want to interrupt or stop the treatment press the **STOP** key.

PROGRAMMING EQUIPMENT

Exemple:

1. Turn the equipment on to start the standard default procedure. Let us suppose that the existing clinical practice or literature suggests, for a particular pathology, the pulsed vacuum mode with 10 pulses per minute, application time of 20 minutes and intensity of approximately -250mmHg.

Figure 11. Liquid Crystal Display, equipment default.

2. Using the **BACK**/**NEXT** keys, scroll down the other parameters and select the values shown in the example.

3- Choosing the pulsed vacuum mode with 10 pulses per minute: Press the **SET+** key until the **VACUUM MODE** field shows PULSE/MIN: 10. At this moment, the liquid crystal display will indicate:

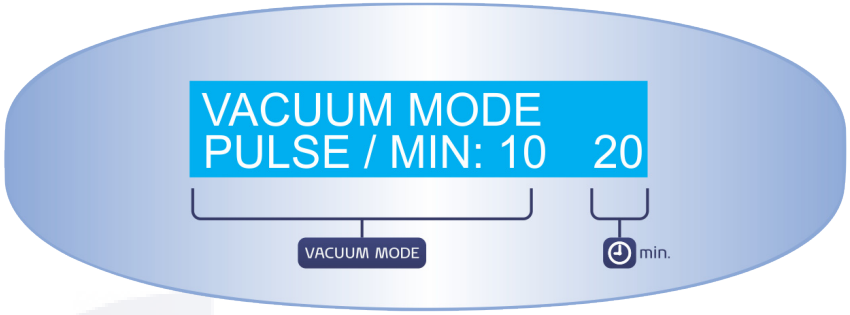


Figure 12. Liquid crystal display example 1, parameter adjustment -application time (20 minutes).

4- Using the **NEXT/BACK** and **SET+/SET-** keys, select the TIMER field (application time), 20 minutes.

5- Now press the **START** key to start the treatment. Note that the 'flashing' cursor will disappear and the vacuum pump is started. Turn the vacuum intensity control until the indicator of vacuum quantity shows approximately -250 mm/Hg. At the end of the programmed time the vacuum pump will be turned off and a sound alarm will indicate the end of the treatment. Press the **STOP** key to stop the alarm.

PLACEMENT OF MICROCRYSTAL INSIDE THE STORAGE TAN

- Remove the microcrystal tank by turning the unit counterclockwise.
- Using the sieve, pour the microcrystals up to approximately ¾ of the storage tank (maximum level).
- We suggest the use of medium grammature microcrystals (approximately 150 microns).
- Put the microcrystal tank back onto the device, this time turning it clockwise.
- The microcrystals, when at rest, even when in closed reservoirs, may absorb humidity, creating small clusters. Always put the crystals through the sieve before placing them inside the microcrystal storage tank.
- At the end of the work cycle, empty the storage tank, and keep it clean.

Note: The microcrystal storage tank, the waste container and the protective air filter unit for vacuum mode operation have a rubber sealing ring close to the screw top. Always check if the sealing rings are positioned correctly before screwing them on.

- Examine the skin and clean the treatment area.
- Clean the application accessories before and after each therapy session.
- After the procedure it is common that the patient presents hyperemia (in some cases, slight swelling) and hypersensitivity.
- Eventually, crusts may be formed, which should not be removed to avoid scarring or stains.
- Avoid the use of creams and lotions which contain acids up until one month before the treatment.
- Avoid direct exposure to the sun after the treatment.
- Use sunscreen and hydrating creams.
- **BIOCOMPATIBILITY** – of the materials in contact with the patient (ISO 10993-1): IBRAMED declares that the accessories used with the equipment do not cause allergic reactions; there is no risk of harmful effects to the cells or potential skin irritation.

MICRODERMABRASION

Figure 13. Facial application technique with diamond tip pen –Diamond Peeling.

Figure 14. 14 Facial application technique with crystal peeling pen.

Figure 15. Body application technique with crystal peeling pen.

Mechanical Massage

A

B

C

Figure 16. A, B e C, body application technique with cupping spheres.

REFERENCES

Adcock D, Paulsen S, Jabour K, Davis S, Nanney LB, Shack B. Analysis of the effects of deep mechanical massage in the porcine model. Plastic and Reconstr Surg 2001; July: 233-240.

Avram MM. Cellulite: a review of its physiology and treatment. J Cosmet Laser Ther 2004; 6: 181–185.

Chang P, Wiseman BS, Jacoby T, Salisbury AV, Ersek RA. Nonivasive mechanical body contouring: (Endermologie) A one-year clinical outsome study update. Aesth. Plast. Surg. 1998; 22: 145-153.

Ciporkin H, Paschoal LHC. Atualização terapêutica e fisiopatogênica da lipodistrofia Ginóide (LDG) "celulite". São Paulo: Santos; 1992.

Curri SB. Las paniculopatias de estasis venosa: diagnóstico clínico e instrumental. Haumsann, Barcelona, 1991.

Gordon C, Emiliozzi C, Zartarian M. Use of a Mechanical Massage Technique Fibromyalgia: A Preliminary Study. Arch Phys Med Rehabil 2006; 87:145-147.

Hexsel MD, Mazzuco R. Subcision: a treatment for cellulite. Inter J of Dermatol 2000; 39: 539-544.

Karimipour, DJ; Kang, S; Johnson, TM; Orringer, JS; Hamilton, T; Hammerberg, C, Voorhees, JJ; Fisher, G Microdermabrasion: A molecular analysis following a single treatment. J Am Acad Dermatol 2005;52:215-23.

Karimipour, DJ; Kang, S; Johnson, TM; Orringer, JS; Hamilton, T; Hammerberg, C, Voorhees, JJ; Fisher, G. Microdermabrasion with and without aluminum oxide crystal abrasion: A comparative molecular analysis of dermal remodeling. J Am Acad Dermatol 2006; 54: 405-410.

Koblenzer CS. Psychosocial Aspects of Beauty: How and Why to Look Good. Clin Dermatol 2003;21:473-475.

Merlen JF, Curri SB, Sarteel AM. Cellulitis, a conjunctive microvascular disease. Phlebologie. 1979; 32(3):279-282.

Mirrashed F, Sharp JC, Krause V, Morgan J, Tomanek B. Pilot study of dermal and subcutaneous fat strutures by MRI in individuals who differ in gender, BMI, and cellulite grading. Skin Res Tecn 2004; 10: 161-168.

Pavicic T, Borelli C, Korting CH. Cellulite – the greatest skin problem in healthy people? An approach. JDDG 2006; 4: 861–870.

Querlex B, Cornillon C. Jolivet O, Bittoun J. Anatomy and physiology of subcutaneus adipose tissue by in vivo magnetic resonance imaging and spectroscopy: Relationship with sex and presence of cellulite. Skin Res Tech 2002; 8: 118-124.

REFERENCES

Rosenbaum M et al. An exploratory investigation of the morphology and biochemistry of cellulite. Cosmetic 1998; 101: 1934-1939.

Rossi ABR, Vergnanini AL. Cellulite: a review. JEADV. 2000 ; 14: 251-262.
Ryan TJ. Lymphatics and adipose tissue. Clin Dermatol 1995; 13: 493-498.

Sant'Ana E. Aplicação de recursos físicos no pós-operatório de lipoaspiração. Congresso Científico Latino-Americano de Estética, Saúde e Bem Estar. p 102-110.

Savardekar, P. Microdermabrasion. J Dermatol Venereol Leprol. 2007; 73 (4): 277-279.

Segers AM, Abulafia J, Kriner J, Cortondo O. Celulitis. Estudio histopatológico e histoquímico de 100 casos. Med. Cut. ILA 1984; 12:167-172.

Smalls LK, Lee CY, Whitestone J, Kitzmiller WJ, Wickett RR. Quantitative model of cellulite: three-dimensional skin surface topography, biophysical characterization, and relationship to human perception. J Cosmet Sci. 2005;56(2):105-20.

Song, JY; Kang, HA; Kim, Mi-Yeon, Young, MP; Hyung, OK. Damage and Recovery of Skin Barrier Function after Glycolic Acid Chemical Peeling and Crystal Microdermabrasion. Dermatol Surg 2004;30:390–394.

Spencer, JM; Kurtz, ES. Approaches to Document the Efficacy and Safety of Microdermabrasion Procedure. Dermatol Surg 2006;32:1353–13.

Tanaka ED. Atuação da fisioterapia intensiva no grande queimado. Acesso em 06/04/2011 http://www.sobrati.com.br/trabalho26.htm

ACESSORIES ACCOMPANYING DERMOTONUS ESTHETIC

CODE	PRODUCT
03017007	PP Female cable IEC-3 x 0.75x 1500mm
03019012	Fuse 5th 20Ag
03026009	Card of diamond line Fuse Protection
03026054	Coiled tube PU 8x6 Blue
03025102	Filter sieve 18,5mm diameter.
03026060	Suction alkaline glass Facial model straight birdie
030266061	Suction alkaline glass Facial model 18mm telescope
03026062	Suction alkaline glass Facial model 12mm telescope
03026063	Suction alkaline glass Facial model duck beak
03026064	Suction alkaline glass Facial Mode bird
02039396	Adapter kit for cupping / Dermotonus
02039468	Pen kit / Machined peeling hose applicator
03025002	Roller cupping 50mm
03025003	Roller cupping 60mm

CODE	PRODUCT
03025004	Cupping 60mm
03025005	Sphere cupping
03040004	IBRAMED 260410 Digital Operation Manual
02039071	Diamond pen kit
03026046	Aluminum Oxide
03026050	Plastic sieve 1 – 7cm

List of accessories and cable length designed with **Dermotonus Esthetic** equipment for meeting the requirements of electromagnetic compatibility - code accessorie **03017007**.

REPLACEMENT ACCESSORIES

The replacement accessories are designed for use with **DERMOTONUS ESTHETIC**. As you order them, provide the respective codes, description and quantity desired.

The use of accessories, cables and transducer Other than the ones destined for this specific equipment may degrade significantly the performance and immunity. Do not use accessories, cables and transducer of **DERMOTONUS ESTHETIC** in other equipment or electromedical systems.

What may initially appear to be a problem not always is really a defect. Therefore, before turning to technical assistance, check the items described in the table below.

PROBLEMS	SOLUTION
The equipment does not turn on 1.	• Is the power cable properly connected? If it is not, it is necessary to connect it. Also check the socket on the wall.
The equipment does not turn on 2.	• Have you checked the safety fuse? Check if there is a bad contact. Check if the value is correct as stated in the instructions.
The equipment is turned on but it does not suck 1.	• Have you followed the recommendations of the instructions to use the equipment correctly? Check them and repeat the steps in the controllers, indications and op-eration section.
The equipment is turned on but it does not suck 2.	• Have you checked the vacuum applicator connections, quick coupling of the coiled hose, and the connection of the crystal tank storage and air filter? • Check if the air filter and the crystal tank storage are adequately tight-ened "screwed"?
The equipment does not turn on and/or it works but it looks like weak.	• Check the quick coupling of the coiled hose, the tightness of the con-nections of the cupping and the crystal tank storage.

WARRANTY TERM

1) IBRAMED warrants that this product is free of manufacturing defects for eighteen (18) continuous months provided the set terms presented in these instructions for use are followed.

2) The warranty period takes effect from the date of purchase and applies to the original purchaser only, even in the event of a product being transferred to a third party.
The warranty covers the replacement of component parts and labor required to repair defects whenever the presence of such manufacturing defects can be determined.

3) Customer Service during the warranty period will be provided exclusively at IBRAMED sale points by IBRAMED itself or another agent designated by the manufacturer.

4) The warranty does not cover damage caused to the product resulting from:
a) Failure to follow the specifications and recommendations detailed in these instructions for use during installation or use of the product.
b) Accidents or acts of God, connections to electrical system with inappropriate voltage and/or subjected to excessive fluctuation or overcharge.
c) Misuse, lack of reasonable care, product alterations, modifications or repairs undertaken by individuals or entities not authorized by IBRAMED.
d) Removal or adulteration of the equipment serial number.
e) Damage during Transport.

5) The legal warranty does not cover: expenses incurred during product installation or transport to the plant or sale point, labor, materials, parts and adjustments necessary to the readiness of the premises in view of the installation of the device, such as but not limited to electric net, masonry, hydraulic network, grounding system, as well as their requirements.

6) The warranty does not cover parts subjected to natural wear, such as but not limited to control buttons, control keys, handles and moving parts, cables, connectors, device cabinets.

7) The selling points are neither authorized to alter the conditions mentioned in this document nor to take any commitment on behalf of IBRAMED.

TECHNICAL ASSISTANCE

If you have any doubts or problems related to the operation of your equipment please contact our technical department.
Call: 19 3817.9633.

DANGER

Do not alter this equipment. Any unauthorized modification can affect the safety of this equipment.

Never make unauthorized repairs.

IBRAMED Equipment goes beyond technology. It also provides knowledge! Science constitutes our differential value and we effectively take advantage of its benefits in order to ensure patient safety and thereby maximize results.

Access to the knowledge database is guaranteed by CEFAI (IBRAMED Center for Education and Advanced Training) whose goal is to provide technical and scientific support as well as current literature on therapies and their applicability while our treatment choices are always thoroughly selected according to the best and latest clinical criteria.

IBRAMED Scientific Committee designs scientific support in view of developing new products and services and so all our equipment and actions are based on the results of the most recent medical studies published in major scientific
journals.

CEFAI takes into account the personal and professional development of all its partners and customers. With our "Hold My Hand" concept, we invite both students and professionals in the fields of Physical Rehabilitation, Esthetics, Physiotherapy, Dermatology and Esthetic Medicine to take part in free courses, workshops, and the best Postgraduate Lato Sensu courses in the areas of physical rehabilitation and esthetics.

Special attention is also given to those interested in visiting our structure. Whatever your professional development needs, we'll be right by your side to provide you with unconditional support.

We are happy to assist you!

www.conexaocefai.com.br
Contact – cefai@conexaocefai.com.br
+55 19 3808 2348

Thanks,

ct!

IBRAMED

QUESTÃO DE RESPEITO

IBRAMED
Indústria Brasileira de Equipamentos Médicos EIRELI
Av. Dr. Carlos Burgos, 2800 - Jd. Itália
13901-080 - Amparo - SP - Brasil
+55 19 3817 9633
www.ibramed.com.br
ibramed@ibramed.com.br